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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2014-0684; FRL-9918-27]

Discarded Polyvinyl Chloride; TSCA Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document announces the availability of EPA's response to a petition it received under the Toxic Substances Control Act (TSCA). The TSCA section 21 petition was received from the Center for Biological Diversity (CBD) on July 29, 2014. The petitioner requested that EPA initiate rulemaking under TSCA to address risks related to polyvinyl chloride (PVC), vinyl chloride, and phthalates used as plasticizers. The petitioner alternatively requested that EPA initiate rulemaking under TSCA to require additional toxicity testing of these chemical substances. After careful consideration, EPA has denied the TSCA section 21 petition for the reasons discussed in this document. The TSCA section 21 petition was accompanied by an independent petition for EPA to take action under the authority of the Resource Conservation and Recovery Act (RCRA). EPA continues to review the petitioner's requests for action under RCRA.

DATES: EPA's response to this TSCA section 21 petition was signed October 24, 2014..

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Paul Lewis, Chemical Control Division (7405M), Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6738; email address: *lewis.paul@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who produce, or who use PVC, vinyl chloride, or phthalates used as plasticizers, or substitutes for such chemical substances. Since many other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Access Information about this TSCA Section 21 Petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2014-0684, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW. Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. TSCA Section 21

A. *What is a TSCA Section 21 Petition?*

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. 15 U.S.C. 2620(b)(3). A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period. 15 U.S.C. 2620(b)(4).

B. *What Criteria Apply to a Decision on a TSCA Section 21 Petition?*

Section 21(b)(1) of TSCA requires that the petition “set forth the facts which it is claimed establish that it is necessary” to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this TSCA section 21 petition.

III. TSCA Sections 6 and 4

Of particular relevance to this TSCA section 21 petition are the legal standards regarding TSCA section 6 rules and TSCA section 4 rules.

A. TSCA Section 6 Rules

To promulgate a rule under TSCA section 6, the EPA Administrator must find that “there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk.” 15 U.S.C. 2605(a). This finding cannot be made considering risk alone. Under TSCA section 6, a finding of “unreasonable risk” requires the consideration of costs and benefits. Furthermore, the control measure adopted is to be the “least burdensome requirement” that adequately protects against the unreasonable risk. 15 U.S.C. 2605(a).

In addition, TSCA section 21(b)(4)(B) provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): “If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that . . . there is a reasonable basis to conclude that the issuance of such a rule . . . is necessary to protect health or the environment against an unreasonable risk of injury,” the court shall order the EPA Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B). Also relevant to the issuance of regulations under TSCA section 6, TSCA section 9(b) directs EPA to take regulatory action on a chemical substance or mixture under other statutes administered by the Agency if the EPA Administrator determines that actions under those statutes could eliminate or reduce to a sufficient extent a risk posed by the chemical substance or mixture. If this is the case, the regulation under TSCA section 6

can be promulgated only if the EPA determines that it is in the “public interest” to protect against that risk under TSCA rather than the alternative authority. 15 U.S.C. 2608(b).

B. TSCA Section 4 Rules

To promulgate a rule under TSCA section 4, EPA must make several findings. In all cases, EPA must find that data and experience are insufficient to reasonably determine or predict the effects of a chemical substance or mixture on health or the environment and that testing of the chemical substance is necessary to develop the missing data. 15 U.S.C. 2603(a)(1). In addition, EPA must find either that:

1. The chemical substance or mixture may present an unreasonable risk of injury or

2. The chemical substance is produced in substantial quantities and may either result in significant or substantial human exposure or result in substantial environmental release. 15 U.S.C. 2603(a)(1).

In the case of a mixture, EPA must also find that “the effects which the mixture’s manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture.” 15 U.S.C. 2603(a)(2).

IV. Summary of the TSCA Section 21 Petition

A. What Action Was Requested?

On July 29, 2014, the CBD submitted to EPA a “Petition for Rulemaking Pursuant to Section 7004(a) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6974(A), and Section 21 of the Toxic Substances Control Act, 15 U.S.C. § 2620,

Concerning the Regulation of Discarded Polyvinyl Chloride and Associated Chemical Additives” (Ref. 1). (The petitioner stated that it was submitting two “independent and fully severable” petitions: One under RCRA and another under TSCA. At this time, EPA is only responding to the TSCA section 21 petition. EPA continues to review the petitioner’s requests for action under RCRA.)

The TSCA section 21 petition states that it is requesting issuance of “regulations governing the safe treatment, storage and disposal of polyvinyl chloride (“PVC”), vinyl chloride and associated dialkyl- and alkylarylestere of 1,2-benzenedicarboxylic acid, commonly known as phthalate plasticizers.” In its conclusion, the petitioner urges EPA to “promptly exercise its authority to ensure the safe disposal of discarded PVC.”

The petitioner requested that EPA initiate rulemaking under TSCA section 6 “to reduce the unreasonable risk to public health and the environment associated with continued dependence” on PVC, vinyl chloride, and phthalates used as plasticizers. The petitioner also alternatively requested that EPA take action under TSCA section 4 “requiring manufacturers and processors responsible for the generation of these compounds to undertake additional toxicity testing” if “the Agency concludes that there are insufficient data and experience upon which to determine or predict the effects of ubiquitous contamination” for purposes of making a TSCA section 6 determination.

EPA interprets the TSCA section 21 petition as requesting EPA to initiate a proceeding for the issuance of a rule under TSCA section 6 to address risks related to the disposal of PVC. The TSCA section 21 petition is unclear about whether it is referring to PVC resins or PVC-based products, but, due to its emphasis on risks created by widespread disposal, EPA assumes the TSCA section 21 petition is about PVC-based

products (i.e., plastics manufactured from PVC resin). EPA therefore interprets the TSCA section 21 petition as arguing that TSCA regulation of the disposal of PVC-based products is necessary in order to address certain post-disposal risks (including risks relating to chemical substances that the petitioner believes could be released by PVC-based products after disposal).

Due to a lack of specificity regarding the particular action requested, and other grounds described in Unit V., EPA denied the TSCA section 21 petition to initiate rulemaking under TSCA section 6 to address risks from the disposal of PVC. As a part of its analysis, EPA also considered whether a broader interpretation of the TSCA section 21 petition, as furthermore requesting regulation of the manufacture, processing, distribution, or use of PVC, would have altered the Agency's decision. EPA considered whether the facts set forth in the TSCA section 21 petition established that it was necessary to initiate TSCA section 6 rulemaking to ban or otherwise limit any specific use of PVC or vinyl chloride, phthalates as plasticizers, or metal-based heat stabilizers in manufacturing PVC as a means of reducing the quantities of such chemical substances that enter the disposal stream in the first place. As described in Unit V., EPA concluded that, under such a broader interpretation, EPA would have denied the TSCA section 21 petition on similar grounds. The TSCA section 21 petition does not clearly state a pre-disposal risk management action that is sought, let alone demonstrate a risk that is unreasonable.

Finally, EPA notes that it did not construe the petitioner's request for rulemaking under TSCA section 4 as a strictly contingent request, which EPA would only consider if it had previously reached particular factual conclusions on its own initiative (i.e., "that

there are insufficient data and experience upon which to determine or predict the effects of ubiquitous contamination”). Therefore, no inference of implicit agreement with such conclusions should be drawn from the fact that EPA has reviewed whether the TSCA section 21 petition itself sets forth facts sufficient to justify the initiation of rulemaking to require toxicity testing under TSCA section 4.

B. What Support Does the Petitioner Offer?

The petitioner states that PVC, vinyl chloride, and phthalates used as plasticizers pose “significant threats” to human health and the environment. While the TSCA section 21 petition includes information on other chemical substances related to PVC (e.g., stating that vinyl chloride is also a concern), it focuses on the use of phthalates as plasticizers in PVC. The TSCA section 21 petition states that phthalates are the most abundant manmade chemicals in the environment and that “virtually universal” exposure to phthalates “could be the leading cause” of human reproductive disorders. The petitioner expresses concern that “these compounds” bioaccumulate in living organisms, interfere with hormone regulation, and alter sexual development. The petitioner also expresses concern that “human contamination probably exceeds previously published estimates” and that harm might be occurring from “exposure pathways outside the scope of traditional toxicity testing,” such as “synergistic” effects from “multiple phthalates” or other pollutants. Finally, citing a single study, the petitioner also states that “less harmful alternatives” to these chemical substances are available.

V. Disposition of TSCA Section 21 Petition

After careful consideration, EPA denied the petitioner’s request to initiate a TSCA section 6 rulemaking, because the TSCA section 21 petition does not:

- Specify what risk management action it is requesting,
- Set forth sufficient facts to establish that the disposal of PVC, vinyl chloride, or phthalates used as plasticizers presents or will present an unreasonable risk, or
- Explain why action under TSCA would be preferable to action under other statutory authorities.

EPA also denied the petitioner's request to initiate a TSCA section 4 rulemaking to require further toxicity testing of PVC, vinyl chloride, or phthalates used as plasticizers, because the TSCA section 21 petition does not set forth sufficient facts for EPA to find that the toxicity information available to the Agency is insufficient to permit a reasoned evaluation of the health or environmental effects of these PVC constituents, or for EPA to conclude that toxicity testing is necessary to develop any missing data.

A. Request for a Rule under TSCA Section 6

With respect to its request that EPA initiate a proceeding for the issuance of a rule under TSCA section 6 to address risks related to the manner of disposal of PVC, the TSCA section 21 petition's primary deficiencies are its failure to specify the risk management action sought and its failure to discuss several major issues intrinsic to an unreasonable risk determination (i.e., risk reduction that would be accomplished by such action and the reasonably ascertainable economic and other social consequences of the action).

Section 21 of TSCA authorizes any person to petition EPA for the "issuance . . . of a rule" under TSCA section 6. As EPA interprets this provision, asking for a rule entails telling EPA, with reasonable specificity, what action is sought in the TSCA section 21 petition. Simply citing to general legal authority and stating a desired outcome

does not define an action, and thus fails this threshold requirement under TSCA section 21. EPA's interpretation is consistent with the short 90-day deadline for responding to such rulemaking petitions, as well as with TSCA's grant of *de novo* judicial review to petitioners. In any such proceeding, it would be necessary to supply the court with a specific description of the relief sought to inform any requested injunction that EPA "initiate the action requested by the petitioner." See 15 U.S.C. 2620(b)(4)(B). Since the court's *de novo* review is itself a rehearing of the Agency's prior review of the TSCA section 21 petition, it follows that the TSCA section 21 petition itself must supply the specific description of the relief sought.

Although the TSCA section 21 petition asserts that "the inadequate management of PVC, vinyl chloride, and phthalate plasticizers poses significant threats to human and ecosystem health," the petitioner's argument as to the existence of unreasonable risk is hindered by a nearly complete lack of detail as to the TSCA risk management that it is seeking. While the petitioner stated the overall outcome that it hoped could be achieved (reduce risk to human health and the environment from the disposal of PVC), the petitioner did not state, in any reasonable manner, what action available under TSCA section 6 it sought in order to achieve that outcome.

The TSCA section 21 petition, furthermore, failed to set forth sufficient facts bearing on the relative risk reduction and the reasonably ascertainable economic and other social consequences of the unspecified risk management action. These issues are integral to EPA's assessment of whether rulemaking under TSCA section 6 is necessary and, even more fundamentally, its assessment of whether a particular risk is in fact an unreasonable risk. This is because the finding of unreasonable risk is a judgement under

which the decisionmaker determines that the risk of health or environmental injury from the chemical substance or mixture outweighs the burden to society of potential regulations (Ref. 2). Because the TSCA section 21 petition omits discussion of multiple issues that are intrinsic to the finding of unreasonable risk, the TSCA section 21 petition fails to set forth sufficient facts to establish that the disposal of PVC, vinyl chloride, or phthalates used as plasticizers presents or will present an unreasonable risk.

Finally, while the petitioner acknowledges that PVC disposal might also be regulated under other EPA statutory authorities, such as RCRA, it has not explained why it believes it would be preferable to address the risks of disposal under TSCA, rather than through other statutory authorities. The petitioner's views on this question are especially difficult to infer given the absence of information about the particular TSCA risk management action sought. This omission is an impediment to assessing whether a TSCA section 6 rule would be an appropriate means of reducing potential risks related to the disposal of PVC, and (if so) how such action could be coordinated, consistent with TSCA section 9(b), with other actions that EPA has already taken with respect to these chemical substances under other statutes that EPA administers.

For example, the petitioner did not explain why it believes vinyl chloride poses an unreasonable risk that should be addressed under TSCA despite the impact of multiple rules regulating this chemical substance under the Clean Air Act (42 U.S.C. 7400 *et seq.*), including one that was recently established in 2012 (Ref. 3). See 40 CFR part 61, subpart F, and 40 CFR part 63, subparts DDDDDD and HHHHHH.

EPA also notes that, if it had construed the TSCA section 21 petition more broadly (i.e., as also seeking actions to address the manufacturing, processing,

distribution in commerce, and use of PVC), then the TSCA section 21 petition's deficiencies would have been multiplied still further, since there would have been even more uncertainty as to the risk management being sought and, thus, even more uncertainty as to the existence of an unreasonable risk that would be necessary to regulate under TSCA section 6.

Though offering some limited information (i.e., noting PVC production volumes, supplying some basic information on the uses of PVC, and citing a paper that lists some possible candidate substitutes for di (2-ethylhexyl)phthalate (DEHP), the TSCA section 21 petition largely omits the sort of information that would be relevant to a cost-benefit and regulatory alternatives analysis for a proposed rule to require the substitution of the chemical substances currently used in the manufacture of PVC. The TSCA section 21 petition provides almost no information on the usefulness and effectiveness of particular substitutes, their relative toxicity, cost, degree of availability, and potential to reduce risk. The TSCA section 21 petition also does not include any information on the costs and benefits of regulatory alternatives to explain why the petitioner believes any particular risk management action is the least burdensome requirement that adequately protects against an unreasonable risk.

For example, the TSCA section 21 petition lacks a meaningful discussion of the feasibility and implications of replacing vinyl chloride, any particular phthalate currently used as a plasticizer in PVC, or any particular heat stabilizer currently used in PVC. While the petitioner makes a passing reference to "the availability of less harmful alternatives," the TSCA section 21 petition does not identify any specific chemical substance as a reasonable substitute for any other chemical substance currently in use in

PVC products. In support of its general suggestion that “less harmful alternatives” are available, the TSCA section 21 petition cites only a single study, which was itself limited to reviewing “candidates” for replacing one specific phthalate (DEHP). The review itself was, furthermore, limited to assessing how well the candidate chemical substances satisfied leachability criteria (Ref. 4).

EPA published an action plan for phthalates in 2009. For purposes of the plan, EPA identified eight phthalates as appropriate subjects for development of an assessment and management strategy: butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), DEHP, diisobutyl phthalate (DIBP), diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), di-*n*-pentyl phthalate (DnNPP), and di-*n*-octyl phthalate (DnOP). See, <http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/phthalates.html>. EPA’s Phthalates Action Plan (Ref. 5) already observes that there are “various *possible* alternatives of phthalates in plasticized PVC.” See, http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates_actionplan_revised_2012-03-14.pdf. While the study cited by the petitioner is consistent with EPA’s prior observation, the TSCA section 21 petition has not set forth facts (e.g., bearing on relative risks, benefits, utility, and cost) to establish that a TSCA section 6 rule requiring the replacement of particular PVC plasticizers in one or more particular applications would be necessary.

B. Request for Action under TSCA Section 4

Apparently anticipating that EPA might deny its request to issue a TSCA section 6 rule on the grounds that there are not sufficient toxicity data to justify a section 6 rule, the petitioner asked EPA to alternatively adopt a rule under TSCA section 4 requiring

manufacturers and processors of PVC, vinyl chloride, and phthalate plasticizers “to undertake additional toxicity testing.”

EPA’s denial of the request to issue a TSCA section 6 rule is not predicated on a determination that there are insufficient toxicity data to justify action under TSCA section 6. Furthermore, the TSCA section 21 petition’s failure to set forth evidence to justify the necessity of rulemaking under TSCA section 6 is not in itself evidence that the currently available toxicity information is inadequate. As noted in Unit IV.A., many of the information gaps in the submitted TSCA section 21 petition are either unrelated, or only indirectly related, to the toxicity of these chemical substances. And the petitioner does not contend that its efforts to explain why rulemaking under TSCA section 6 is necessary were impeded by a lack of information about the toxicity of these chemical substances.

EPA is denying the request for rulemaking under TSCA section 4 because the TSCA section 21 petition does not set forth sufficient facts for EPA to find that the toxicity information available to the Agency is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemical substances, or for EPA to conclude that toxicity testing is necessary to develop any missing data.

Although the petitioner suggests in very general terms that “[non-]traditional toxicity testing” might produce results showing that these chemical substances are riskier than currently known, the petitioner does not identify any particular deficiency in what is currently known about the toxicity of these chemical substances, or specify what kind of “non-traditional” toxicity tests the petitioner believes are necessary. Neither does the TSCA section 21 petition indicate whether (and if so, why) the petitioner believes that any deficiencies in the availability of information about the toxicity of these chemical

substances are precluding a reasoned evaluation of health or environmental effects. Even if the TSCA section 21 petition had established that the currently available toxicity information could be improved in particular respects for one or more of these chemical substances, it would not automatically follow that the currently available toxicity information is insufficient to permit a reasoned evaluation of health or environmental effects.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. CBD. Petition for Rulemaking Pursuant to Section 7004(a) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6974(A), and Section 21 of the Toxic Substances Control Act, 15 U.S.C. § 2620, Concerning the Regulation of Discarded Polyvinyl Chloride and Associated Chemical Additives. July 29, 2014.

2. EPA. Lead Fishing Sinkers; Response to Citizens' Petition and Proposed Ban; Proposed Rule. **Federal Register** (59 FR 11122, March 9, 1994) (FRL-4643-3).

3. EPA. National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production; Final Rule. **Federal Register** (77 FR 22848, April 17, 2012) (FRL-9636-2).

4. Kastner *et al.* Aqueous leaching of di-2-ethylhexyl phthalate and 'green' plasticizers from poly(vinyl chloride). *Science of the Total Environment*. p. 432. 2012.

5. EPA. Phthalates Action Plan. Revised. March 14, 2012.

List of Subjects in Chapter I

Environmental protection, Hazardous substances, Phthalates, Plasticizers, Polyvinyl chloride, Vinyl chloride.

Dated: October 24, 2014.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.